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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,905	07/18/2003	Ronit Yahalomi	1662/611051	2837

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KENYON & KENYON LLP
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NEW YORK, NY 10004

EXAMINER

VALENROD, YEVGENY

ART UNIT	PAPER NUMBER
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1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/622,905

Applicant(s)

YAHALOMI ET AL.

Examiner

Yevgeny Valenrod

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) 1-40 and 55-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-54 and 97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claims 84 and 86 are withdrawn as directed to non-elected subject matter.

Rejection of claim 53 made under 35 USC 112 first paragraph is withdrawn in view of applicants' amendment.

Rejection of claims 41-49 made under 35 USC 112 1st paragraph is withdrawn in view of applicants argument.

Rejection of claims 51 and 52 under 35 USC 112 1st paragraph is withdrawn in view of applicants' arguments

Rejection of claims 53-54 under 35 USC 112 1st paragraph is withdrawn in view of applicants' arguments.

Double patenting rejections are maintained.

The new grounds for the following 112 2nd paragraph rejections were **not** necessitated by applicants' amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 52 recites the following temperatures: 20vC and 30EC. It is unclear what units the temperature is measured in. In order to advance the prosecution examiner will interpret the temperature to be in °C.

2. Claims 41-49 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Elements of the process such as temperatures at which each individual step is performed, duration of stirring the solution, solvent/anti-solvent ratio and relative temperatures, pH of the solution, temperature and pressure at which the product is dried are critical or essential to the practice of the invention, but not included in the claims. Formulations of Nateglinide are readily converted from one form to another by heating. Also, obtaining the various forms of nateglinide is achieved by varying temperature and crystallization/precipitation procedures. Without providing the exact conditions required to make the specific form, in this case form U, one of ordinary skill in the art would have to perform undue experimentation in order to practice the claimed invention. For example, merely stating "crystallizing nateglinide form U from the solution" as applicant does in claim 41 part "b" does not provide adequate guidance as to how one should practice the invention. In the specification on page 17 line lines 16-22, applicant discusses the effects of solvent/anti-solvent on the form of nateglinide obtained via crystallization. In the same paragraph the effects of prolonged crystallization are discussed. According to the specification: Form E can be obtained from toluene/methanol mixture, Forms B and Z are recovered from heptane/ethyl acetate mixture and forms B and H are obtained from toluene/ethyl acetate. Claim 49 contains the strictest limitations of the claims that depend directly or indirectly on claim 41. Yet, even claim 49 fails to provide adequate guidance. The claim states that the

Art Unit: 1621

product should be recovered before its transition to another form, but does not provide any limitation on the time it takes for the product to undergo the said transition. The sensitivity of the polymorphic form obtained to conditions of the crystallization process is exemplified in Table XI on page 37 of the specification. Last two table entries provide conditions for preparation of form U and form Theta. Form U is obtained at .77:1 solvent/antisolvent ratio and 22 hours at 25°C. While form Theta is obtained at 0.88:1 solvent/antisolvent ratio and 21 hours at decreasing temperature from 45 to 25. From those results it is clear that the cooling period and solvent/antisolvent ratio are essential to obtaining a particular polymorphic form. Examiner suggests amending claim 41 and its dependant claims to include conditions that are essential to preparation of form U.

3. Claims 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The temperature and the duration of crystallization are critical or essential to the practice of the invention, but not included in the claims. On pages 19-20 the applicant provides a table of conditions and forms of nateglinide obtained as a result of applying a given set of conditions. From Entry 4 on page 20, one can see that by merely stirring the solution after crystallization various forms can be form obtained. For example: H is obtained directly after crystallization, U after stirring for 1-5 hr. and δ after stirring for more than 5 hr. To enable the disclosure of these claims applicant needs to include the limitations, which would allow one skilled in the art to practice the invention without unnecessary experimentation. These

Art Unit: 1621

limitations include: ranges that would define the terms "suited temperature" and "sufficient amount of time".

4. Claims 53-54 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Temperature at which crystallization occurs, the cooling rate of the nateglinide solution, and duration of crystallization are critical or essential to the practice of the invention, but not included in the claims. On p 18 lines 13-21 of the disclosure, the applicant describes conditions that are favorable for formation of form U. These conditions include: stirring for about 1 hour, but no more than 5 hours; crystallization and filtering temperatures of -15 to 10°C, starting with a temperature of 25-35°C followed by cooling in 1 hour to -15 to 10°C. These or other limitation that find support in the specification should be included in the claim language.

Provisional Double Patenting

5. Claim 97 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 101 of copending Application No. 10/693166. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In the instant application, form U has FTIR peaks at 3350, 1701, 1646 and 1291 cm⁻¹, (see Figure 31) same as recited in claim 101 of Application No. 10/693166. If the applicant alleges that the product results from a different process, it is the

Art Unit: 1621

examiners position that process by which the product was made is not a sufficient difference to make the alleged different products patentably distinct.

6. Claim 97 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 102 of copending Application No. 10/693166. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In the instant application, form U has FTIR identical to the one recited in claim 102 of Application No. 10/693166 (see Figure 31 of the instant application and Figure 31 of the Application No. 10/693166). If the applicant alleges that the product results from a different process, it is the examiners position that process by which the product was made is not a sufficient difference to make the alleged different products patentably distinct.

7. Claim 97 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 97 of copending Application No. 10/693166. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In the instant application, form U has peaks at: 3.8, 4.8, 7.5, 13.8 and 17.00 (figure 17) as is claimed in the claim 97 of Application No. 10/693166.

8. Claim 97 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 97 of copending Application No. 10/693166. This is a provisional double patenting rejection since the conflicting claims have not in fact been

Art Unit: 1621

patented. In the instant application, form U has XRPD pattern represented by figure 17, said pattern is substantially depicted in Figures 65-68 of Application No. 10/693166.

9. Claim 53 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 10/746697. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. In the instant application, form U has XRPD pattern represented by figure 17, said pattern contains peaks at: 4.6, 7.4, 13.8 and 17. The instant and the reference application are therefore applications, which are concerning the preparation of the same Form of nateglinide. Claim one of the reference application claims preparation of a specific form of nateglinide, which is characterized by the XRPD peaks as listed above. The said form is prepared by: preparing a solution in ethyl acetate, seeding the solution with nateglinide crystals, and recovering the crystalline form as a precipitate. Instant claim 53 recites the same steps for preparing Form U. Since all the limitations of claim 53 are met by claim 1 of the co-pending application #10/746697, claim 53 is rejected under provisional double patenting.

Non-statutory/obviousness type

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

Art Unit: 1621

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 97 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 97 and 98 of copending Application No. 10/693166. Although the conflicting claims are not identical, they are not patentably distinct from each other because the XRPD pattern of Form U in the

Art Unit: 1621

instant application has peaks at: 4.8, 7.5, 13.8 and 17.00 (figure 17) as is claimed in the claim 97 of Application No. 10/693166. There is also a peak at 3.8, which although reduced, is also present in the reference application. The term "substantially reduced" used in claim 97 of the reference application, does not render the invention patentably distinct from instant the claim 97.

The same peaks (4.8, 7.5, 13.8 and 17.00) show up in the XRPD pattern of Figures 65-68 of No. 10/693166. Compared to Figure 17 of the instant application, the location of the peaks in Figures 65-68 of No. 10/693166 is identical, however, the intensity of the peaks slightly varies. Nonetheless, the difference in the XRPD patterns is not sufficient to render the crystalline forms represented by the said XRPD patterns patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-97 are pending

Claims 1-40 and 55-96 are withdrawn


Claims 41-54 and 97 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

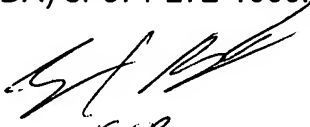
Art Unit: 1621

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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